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09/582,808	10/16/2000	Ib Mendel-Hartvig		2872

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,808	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- Th MAILING DATE of this communication appears on th cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the claims

The amendment filed on September 4, 2002 is acknowledged and has been entered.

Claim Objections

1. Claims 43-83 are objected to because of the following informalities: "--" is placed at the beginning and end of each claim. It is suggested to remove "--" Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 42-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 part (B) "via" is vague and indefinite. It is unclear what the term encompasses. See also deficiency found in claim 63.

Claim 43, line 2 "complex mixture" is vague and indefinite. It is unclear what complex mixture comprises. Does complex mean the formation of a complex between an analyte and its specific binding partner or does complex mixture mean different molecules or does it mean something else.

Claim 60, line 4 "may be" is vague and indefinite. Does the Capturer bind by biospecific affinity or not? See also deficiency found in claim 81.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 42-47, 51,-53, 56-57, 59-61, 63-68, 72-74, 77-78, and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al (US 5,989,921) in view of Porrvik et al (US 5,902,834).

Charlton et al disclose an immunoassay method for determining the presence of a ligand (analyte) in a sample. Charlton et al disclose applying a sample to an inlet of a test device which comprises a sorbent material which defines a lateral flow path, capable of transporting an aqueous solution by capillary action to a test site (detection zone). Charlton et al disclose that a conjugate comprising a protein bound to a colored particle (Reactant*) is mixed with the sample and inserted into the test device. Charlton et al also disclose that the conjugate may be predeposited in the test strip upstream of the test site (detection zone). Charlton et al disclose that the conjugate and sample flows to the test site (detection zone), which comprises latex particles entrapped or fixed in the flow path having an immobilized protein (antibody)(capturer) on their surface. Charlton et al disclose that if the analyte is present it reacts with immobilized binding protein (antibody) at the test site and forms a sandwich comprising immobilized binding protein-ligand binding protein colored particle (Reactant*) (col 3, line 21 – col 4, line 67). Charlton et al disclose that the color particles have a size of 18 nm (0.018 um) (col 8,

lines 16-18). Charlton et al disclose that that beads trapped in the test site have a size of 0.3 microns. Charlton et al also disclose packing the components into a test kit (col 4, line 17). Charlton et al disclose that the test cell can be used to detect any ligand (analyte) which has been assayed using known immunoassay procedures, or known to be detectable by such procedures (col. 4, lines 29-37).

Charlton et al differ from the instant invention in failing to teach the immobilized particles which exhibit hydrophilic groups on their surface.

Porrvik et al disclose particles that are hydrophilic and are produced which carry on their internal and external surfaces hydrophilic groups (primarily alcoholic and/or phenolic hydroxyl groups and/or primary, secondary or tertiary amine groups) which have been introduced by adsorption or covalent bonding of a compound contain the groups (col 4, lines 20-43). Porrvik et al disclose that these particles can be used as a solid phase in immunoassays, particularly when the particles are in a hydrophilic form. Porrvik et al shows that these particles will result in an improved flow through the particles, which, in turn, results in improved kinetics (col 1, lines 5-25).

It would have been obvious to one of ordinary skill in the art to incorporate hydrophilic particles as taught by Porrvik et al into the method of Charlton et al because Porrvik et al teach that these particles can be used as a solid phase in immunoassays, particularly when the particles are in a hydrophilic form. Porrvik et al shows that these particles will result in an improved flow through the particles, which, in turn, results in improved kinetics.

5. Claims 48 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al and Porrvik et al in view of Devlin et al (US 5,846,703).

See above for teachings of Charlton et al and Porrvik et al.

Charlton et al and Porrvik et al differ from the instant invention in failing to teach the analyte is an antibody of IgE type with specificity to allergens.

Devlin et al disclose that sandwich techniques can also be used to assay antibodies rather than antigens. Devlin et al also disclose determination of an antigen specific IgE by immobilizing antigens to solid phases. The antigens are biospecific for the corresponding antibody. Devlin et al disclose that these IgE antibodies are directed to an allergen (col 2, line 57 – col 3, line 1). Devlin et al disclose that this immunoassay allows for the measurement of antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

It would have been obvious to one of ordinary skill in the art to incorporate the use of immobilized antigens as taught by Devlin et al into the modified method of Charlton et al because Charlton et al disclose that that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or known to be detectable by such procedures and Devlin et al shows that this immunoassay allows for the detection of IgE and also allows for the measurement of antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

Claims 49, 58, 70 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al and Porrvik et al in view of Dafforn et al (US 4,981,786).

See above for teachings of Charlton et al and Porrvik et al.

Charlton et al and Porrvik et al differ from the instant invention in failing to teach the analyte is an antibody with specificity to autoantigens. Charlton et al and Porrvik et al also differ from the instant invention in failing to teach the application of reagent upstream of a sample application site.

Dafforn et al disclose the application of reagents upstream of a sample application site (col 13, lines 32-44) and also disclose detecting autoimmune antibodies (col 5, lines 1-8). Daffron et al disclose that the application of reagents in this manner and the detection of autoimmune antibodies provides for a device which is simple, rapid, accurate, and safe and avoids contamination of various reagents during their addition to the device (col 2, lines 32-42) and provides for the detection of clinically important proteins (col 4, lines61-68).

It would have been obvious to one of ordinary skill in the art to incorporate the application of reagents and the detection of autoimmune antibodies as taught by Dafforn et al into the modified method of Charlton et al because Dafforn et al shows that the application of reagents in this manner and the detection of autoimmune antibodies provides for a device which is simple, rapid, accurate, and safe and avoids contamination of various reagents during their addition to the device and provides for the detection of clinically important proteins.

Claims 50, 54, 55, 71, 75 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al and Porrvik et al in view of Brown et al (US Patent 5,149,622).

See above for teachings of Charlton et al and Porrvik et al.

Charlton et al and Porrvik et al differ from the instant invention in failing to teach the particles anchoring the capturer have a size, which is smaller than a smallest inner dimension of the flow channels of the matrix.

Brown et al disclose a flow device in which particles having a substance capable of reaction with the analyte in the sample, are immobilized in a matrix. Brown et al disclose that the average diameter of the particles is less than the average pore size of the matrix (see abstract). Brown et al disclose that by having the particle sizes having a size which is smaller than the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay, which is highly advantageous over devices and assay methods of the prior art.

It would have been obvious to one of ordinary skill in the art to incorporate particles which have a smaller diameter than that of the matrix as taught by Brown et al into the method of Charlton et al because Brown et al shows that by having the particle sizes having a size which is smaller that the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay which is highly advantageous over devices and methods of the prior art.

With respect to the flow channels having a smallest inner dimension and inner diameter in the range of 0.4-1000 um as recited in the instant claims, the optimum dimension and diameter

of the flow channels can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980)

Claims 62 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al and Porrvik et al in view of Self et al (US 4,446,231).

See above for teachings of Charlton et al and Porrvik et al.

Charlton et al and Porrvik et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al show that

immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances. Furthermore, Charlton et al disclose that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or known to be detectable by such procedures.

Response to Arguments

Applicant's arguments with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
November 6, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/14/02